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SUBJECT: HEALTH EFFECTS OF PVC PACKAGING

1. BACKGROUND: US ACTIONS ON PVC

SUMMARY OF BACKGROUND: THE STUDY AND REGULATION OF POLYVINYL CHLORIDE (PVC) IN THE UNITED STATES HAS BEEN PRIMARILY IN FOUR AREAS: (A) USE OF PVC IN ALCOHOLIC AND FOOD PACKAGING MATERIALS; (B) VINYL CHLORIDE MONOMER INHALATION OCCUPATIONALLY; (C) USE OF VC MONOMER AS PROPELLANT IN DRUG AND COSMETIC AEROSOL PRODUCTS; (D) PVC USE IN FOOD AND DRUG CONTAINERS.

THE US FOCUS IS NOW ON HEALTH EFFECTS OF RESIDUAL VINYL CHLORIDE MONOMER IN FOOD AND DRUG PACKAGING AND ITS MIGRATION

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TO THE FOOD OR DRUG--AN URGENT PROBLEM OF CONSIDERABLE

SCIENTIFICA AND POLITICAL COMPLEXITY AND HIGH PUBLIC INTEREST.

A. USE OF PVC IN ALCOHOLIC PACKAGING MATERIALS

IN JANUARY 1973, THE FOOD AND DRUG ADMINISTRATION (FDA) BEGAN TO RECEIVE REPORTS OF POSSIBLE STABILITY PROBLEMS WITH PVC BOTTLES USED FOR DISTILLED SPIRITS. THESE BOTTLES WERE PART OF AN EXPERIMENTAL PROGRAM AUTHORIZED BY THE BUREAU OF ALCOHOL, TOBACCO, AND FIREARMS IN NOVEMBER 1968. INDUSTRIAL USERS OF THESE BOTTLES HAD DISCOVERED AN UNPLEASANT TASTE IN LIGHTLY FLAVORED ALCOHOLIC BEVERAGES WHICH HAD BEEN KEPT IN STORAGE. PRELIMINARY ANALYTICAL RESULTS INDICATED THAT VINYL CHLORIDE MONOMER (VC), A COMPONENT OF PVC WHICH MIGHT BE HARMFUL TO HUMANS IF INGESTED, WAS MIGRATING FROM THE BOTTLE TO THE LIQUOR DURING STORAGE. THE LEVEL OF VC MIGRATING VARIED, WITH SOME SAMPLES IN A HIGH RANGE OF 10-20 PPM. AT THAT TIME, THE RESULTS HAD NOT BEEN CONFIRMED BY MASS SPECTROMETRIC EXAMINATION. DURING APRIL A NEW SERIES OF ANALYTICAL RESULTS, INCLUDING MASS SPECTROMETRIC EXAMINATION, WAS PRESENTED TO FDA BY INDUSTRY WHICH CONFIRMED THE EARLY REPORTS OF VC IN VARIOUS DISTILLED SPIRITS. THESE BEVERAGE SAMPLES HAD BEEN STORED IN PVC BOTTLES FOR UP TO ONE YEAR. INFORMATION WAS ALSO RECEIVED WHICH REPORTED THAT WINE PACKAGED IN PVC BOTTLES WAS SIMILARLY AFFECTED. THE FDA CONFIRMED THE MIGRATION OF THE VC MONOMER IN DISTILLED SPIRITS IN ITS OWN LABORATORY. CONSEQUENTLY, ON MAY 17, 1973, THE FDA PUBLISHED IN THE FEDERAL REGISTER A "NOTICE OF PROPOSED RULE MAKING" STATING THAT POLYVINYL CHLORIDE RESINS MEETING CERTAIN CRITERIA MAY BE USED AS A COMPONENT OF FOOD PACKAGING MATERIAL, OTHER THAN PACKAGING MATERIAL FOR USE IN CONTACT WITH ALCOHOLIC FOODS.

B. PROPOSED STANDARD FOR VC BY DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

ON JANUARY 22, 1974, OSHA WAS INFORMED BY THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH) THAT THE B.F. GOODRICH CHEMICAL COMPANY REPORTED THAT DEATHS OF SEVERAL OF ITS EMPLOYEES FROM A RARE LIVER CANCER (ANGIO-SARCOMA) MAY HAVE BEEN OCCUPATIONALLY RELATED. AS A RESULT OF THIS NOTIFICATION, A FACT-FINDING HEARING ON POSSIBLE UNCLASSIFIED

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HAZARDS INVOLVED WITH THE MANUFACTURE AND USE OF VC WAS HELD ON JANUARY 30, 1974. INFORMATION PRODUCED AT THIS HEARING DEMONSTRATED THAT EXPOSURE OF LABORATORY ANIMALS TO VC BY INHALATION, REPEAT INHALATION, AT AND BELOW THE THEN CURRENT OSHA STANDARD OF 500 PPM INDUCED TUMORS, INCLUDING ANGIOSARCOMAS OF THE LIVER. THE EXPERIMENTAL RESULTS REPORTED WERE THAT TUMORS HAVE BEEN OBSERVED IN GROUPS OF ANIMALS EXPOSED TO VC AT CONCENTRATIONS AS LOW AS 250 PPM. NO TUMORS WERE OBSERVED

IN THE GROUP OF ANIMALS EXPOSED TO VC AT A CONCENTRATION OF 50 PPM. IT ALSO APPEARS THAT THE TOTAL NUMBER OF TUMORS, AS WELL AS THE NUMBERS OF ANGIOSARCOMAS OF THE LIVER, DECREASED AS THE CONCENTRATION OF VC WAS REDUCED TO 250.PPM.

ON THE BASIS OF ALL INFORMATION AVAILABLE AT THAT TIME, AND THE FACT THAT EMPLOYEES WERE BEING EXPOSED AT LEVELS AROUND THE EXPERIMENTALLY OBSERVED EFFECT LEVEL OF 250 PPM, AN EMERGENCY TEMPORARY STANDARD WAS PROMULGATED ON APRIL 5, 1974. THIS STANDARD REDUCED THE LEVEL FROM A CEILING OF 500 PPM TO 50 PPM.

ON APRIL 15, 1974, ADDITIONAL INFORMATION AND DATA WERE PRESENTED TO REPRESENTATIVES OF OSHA, NIOSH, AND THE ENVIRONMENTAL PROTECTION AGENCY. ALTHOUGH ONLY PRELIMINARY IN NATURE, THESE RESULTS REVEALED THAT TWO OUT OF 200 MICE EXPOSED TO VC CONCENTRATIONS OF 50 PPM FOR 7 HOURS A DAY, FIVE DAYS A WEEK, FOR APPROXIMATELY 7 MONTHS, DEVELOPED ANGIOSARCOMAS OF THE LIVER. THE QUESTION OF A SAFE LEVEL OF EXPOSURE FOR HUMANS COULD NOT BE DETERMINED IMMEDIATELY AND MAY CONTINUE AS A MATTER FOR SCIENTIFIC DELIBERATION FOR MANY YEARS. THE US DEPARTMENT OF LABOR THEREFORE CONCLUDED, AND PUBLISHED IN THE "FEDERAL REGISTER" OF MAY 10, 1974, THAT IT WAS NECESSARY TO CHANGE THE 50 PPM LEVEL TO AS LOW A LEVEL AS CAN BE DETECTED.

THE PROPOSED PERMANENT STANDARD IS MUCH MORE COMPREHENSIVE THAN THE PROVISIONS OF THE EMERGENCY TEMPORARY STANDARD AND INCLUDES: (A) A "NO DETECTABLE LEVEL OF EXPOSURE;" (B) A MONITORING PROGRAM; (C) CONTROL METHODS (D) MEDICAL SURVEILLANCE (E) RECORDS AND REPORTS.

C. VC AS AN INGREDIENT OF DRUG AND COSMETIC AEROSOL PRODUCTS

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ON APRIL 22, 1974, FDA ISSUED A NOTICE OF PROPOSED RULE-MAKING ON VC AS AN INGREDIENT OF DRUG AND COSMETIC AEROSOL PRODUCTS. THE FDA STATED THAT THE ONLY KNOWN USE OF VC IN DRUG PRODUCTS HAS BEEN AS A PROPELLANT IN AEROSOL PREPARATIONS SOLD OVER THE COUNTER. THE FDA DETERMINED THAT THERE WAS SUFFICIENT SCIENTIFIC DATA ON WHICH TO BASE A DECISION THAT: (A) VC PRESENTS AN UNNECESSARY HAZARD TO THE PUBLIC HEALTH WHEN IT IS USED AS AN INGREDIENT IN COSMETIC AEROSOL PRODUCTS AND THAT SUCH USE SHOULD BE BANNED; AND (B) VC IS NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND IS A NEW DRUG WITHIN THE MEANING OF SECTION 201(P) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT, WHICH REQUIRES AN APPROVED NEW DRUG APPLICATION AS A CONDITION OF MARKETING. IN VIEW OF THE EVIDENCE, THE COMMISSIONER OF THE FDA CONCLUDED THAT THE BANNING OF VC AS AN INGREDIENT IN DRUG AND COSMETIC AEROSOL PRODUCTS IS

REQUIRED.

D. HEALTH EFFECTS OF PVC CONTAINERS

ADVERSE HEALTH EFFECT MAY BE CAUSED IF VC (A GAS) LEAKS FROM THE SOLID PVC CONTAINER INTO THE PRODUCT. THE VC MONOMER GAS IS TRAPPED IN THE MOLECULAR STRUCTURE OF THE PVC SOLID CONTAINER. THE FDA IS PREPARING A PROPOSED REGULATION ON PVC CONTAINERS FOR FOOD, DRUG, MEDICAL DEVICES, BIOLOGICS, COSMETICS AND VETERINARY MEDICINES (RADIO-LOGICAL CONTAINERS ARE NOT INVOLVED). AN FDA TASK FORCE, WHICH UP UNTIL OCTOBER 1974 WAS ORIENTED TO ANALYTICAL PROCEDURES AND EXCHANGE OF INFORMATION HAS, AT THE DIRECTION OF THE FDA COMMISSIONER'S OFFICE, TAKEN ON THE PREPARATION OF PROPOSED REGULATION FOR PVC CONTAINERS. BARRING ANY MAJOR PROBLEMS, THE PROPOSED STANDARDS WILL BE PUBLISHED IN "FEDERAL REGISTER" BEFORE THE END OF 1974. (THESE WILL BE TRANSMITTED TO POSTS FOR INFORMATION OF HOST GOVERNMENTS.) THE SCOPE OF RULEMAKING IN THE PROPOSED DOCUMENT WILL REFER TO CONTAINERS AND MIGRATION OF VC THEREFROM. IT WILL DEAL WITH BOTH THE AMOUNT OF RESIDUAL VC MONOMER IN A PVC CONTAINER AND MIGRATION OF VC TO THE ENCLOSED PRODUCT. A PROPOSED INTERIM STANDARD WILL BE PROPOSED ON THE QUANTITY OF VC ALLOWED IN PVC CONTAINERS. DETERMINATION MUST BE MADE IF PVC CONTAINERS CAN BE MADE WITH LOW AMOUNTS OF VC MONOMER. THE PROPOSED RULE ESSENTIALLY WILL SERVE TO RULE OUT CERTAIN KINDS OF CONTAINERS WITH HIGH VC MONOMER CONTENTS.

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NO SPECIFIC STANDARDS WILL BE SET FOR MIGRATION INTO THE FOOD, ETC., STORED IN THE PVC CONTAINER AT THIS TIME. INGESTION STUDIES ON THE EFFECTS OF VC ARE IN A PRELIMINARY STAGE. THE FDA WILL CALL FOR OTHER WORK DATA, INDUSTRIAL AND SCIENTIFIC ON VC CONTENT AND VC EFFECTS IN EATING STUDIES. THE FDA HAS URGED INDUSTRY TO SUBMIT SUCH DATA ON A VOLUNTARY BASIS AND IS EVALUATING THE DATA WHICH HAS BEEN SUBMITTED. THE DATA SUBMITTED, TO DATE, IS SOMEWHAT DISAPPOINTING, BECAUSE OF DIFFERENCES IN ANALYTICAL TECHNIQUES. THE FDA IS VERY INTERESTED IN THE PROBLEM OF WHAT IS MEASURABLE. THE FDA IS GUIDING STUDIES OF METHODOLOGY FOR DETERMINING THE RESIDUAL VC MONOMER. TESTS ARE BEING CONDUCTED IN TEN DIFFERENT LABORATORIES THROUGHOUT THE US ON A KNOWN RESIN. IN ADDITION, TESTS ARE BEING DONE TO DETERMINE THE RESIDUAL VC MONOMER CONTENT IN BLOOD BAGS. INGERSOLL

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